

LAB -7- CAPSULES



CAPSULES

- Capsule is a solid dosage form consisting from gelatin shell filled with a blend of active ingredient and excipients which may be powder, semisolid or liquid that do not dissolve the gelatin shell.
- There are two types of capsules:



Hard gelatin capsule (HGC)

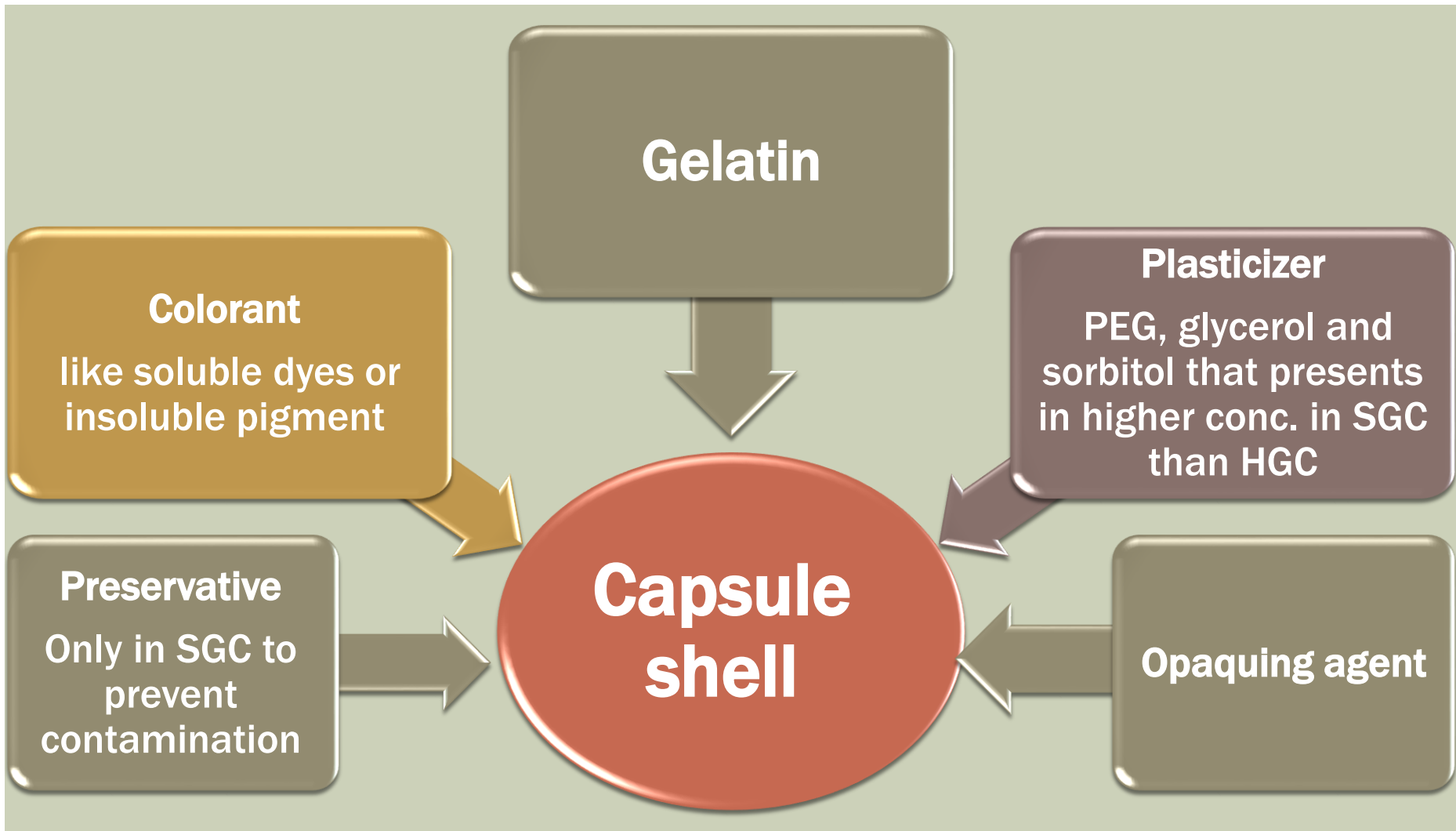
- Which consist of body and cap that filled with powder.



Soft gelatin capsule (SGC)

- Which consist of one piece that is filled with liquid.

CAPSULES



PROPERTIES OF THE GELATIN

1- Non-toxic and widely used in food.

2- Readily soluble in biological fluids and body tissues.

3- Good film forming that undergo reversible phase change from solid to gel in few temperature degree change.

ADVANTAGES OF CAPSULES OVER TABLET



- **1- Mask bitter taste.**




- **2- More convenient for the patient because it is more easily swallowed since they are smooth and slippery.**



- **3- More elegant than tablet.**



- **4- Used for photosensitive drugs.**

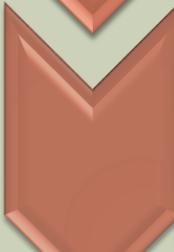


- **5- More economic due to no compression required and less excipients used.**

ADVANTAGES OF CAPSULES OVER TABLET



• 6- No disintegrating agents added.



• 7- No binder added except with the rotary machine in which vegetable oil is used as a binder to prevent dusting.



• 8- Little lubricant used.



• 9- Diluents used to increase bulkiness or to improve flowability and compatibility.

DISADVANTAGES OF CAPSULES

1- Not used for **highly soluble** drugs such as KBr and NH₄Cl since the sudden release of such drugs in the stomach will cause **high irritation**.

2- Not used for **efflorescent** and **deliquescent** materials, since the **efflorescent** materials cause the capsule to **soften**, while **deliquescent** drugs may **dry** the capsule shell to excessive **brittleness**, which can be reduced by using small amount of inert oil in powder mixture.

STEPS FOR PREPARATION

A- Formulation:
Demixing or incompatibility
can be prevented by

- The **demixing** can be prevented by using excipients or diluents with the **same particle size and the density** to prevent segregation.

- Prevent the incompatibility

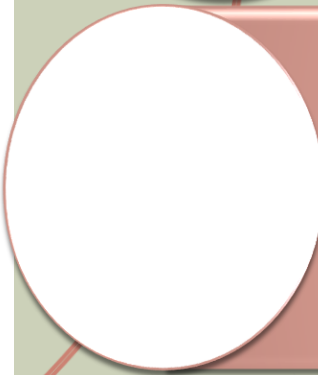
NOTES



- The amount of the diluents depends on the amount of the active ingredient and the size of the capsule.

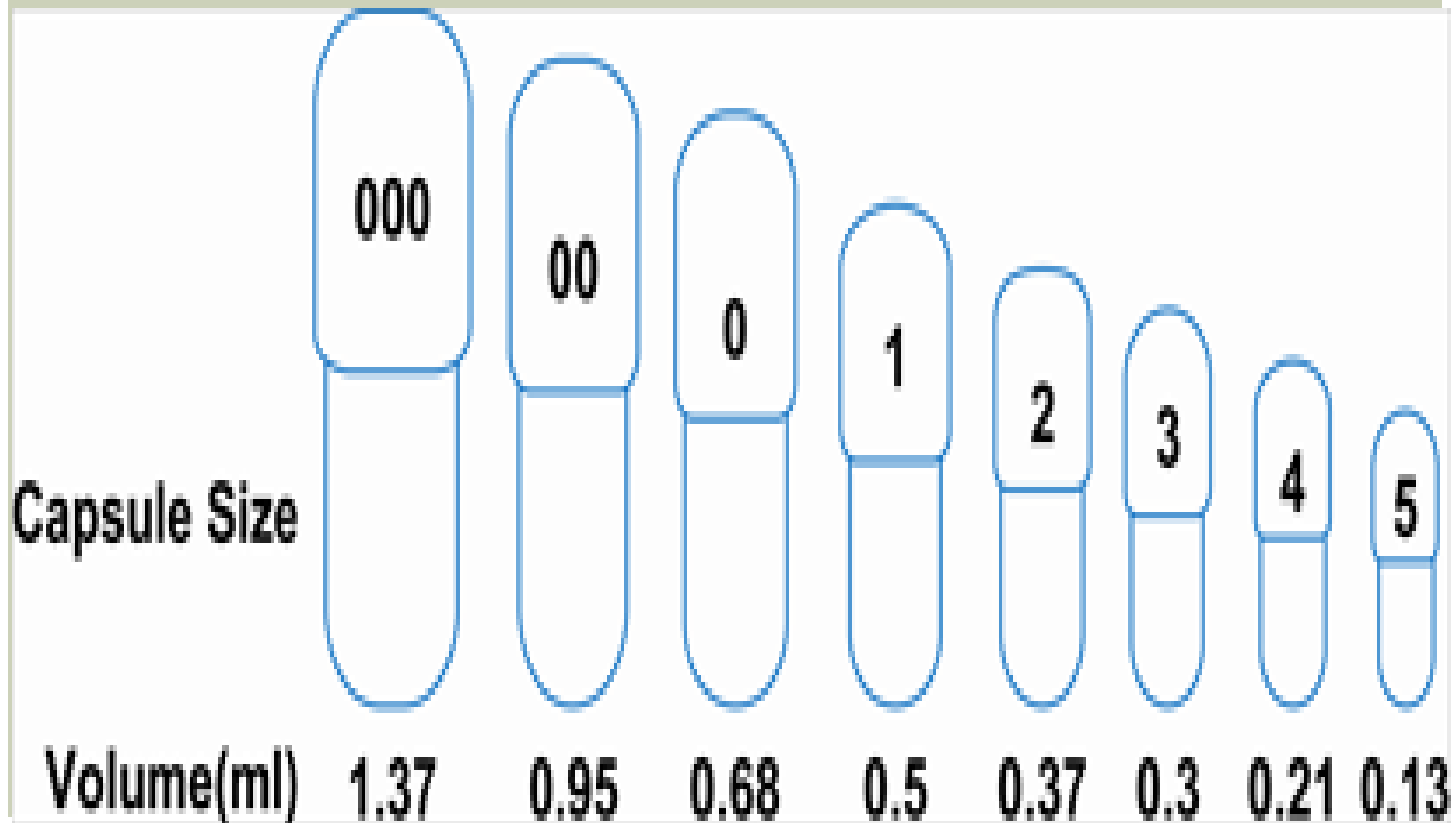


- The hard gelatin capsule have different sizes (000, 00, 0, 1, 2, 3, 4, 5).



- The humidity (moisture content) of the capsule should range between (10-15%) since below 10% the capsule will be brittle and shrink to a point that it will not fit in the filling equipment, while when the moisture content is above 15% the capsule will be so soft and will cause size problems with the loss of mechanical strength.

HARD GELATIN CAPSULES SIZES



STEPS FOR PREPARATION

B- Filling

1- Electrical machine which is automatic.

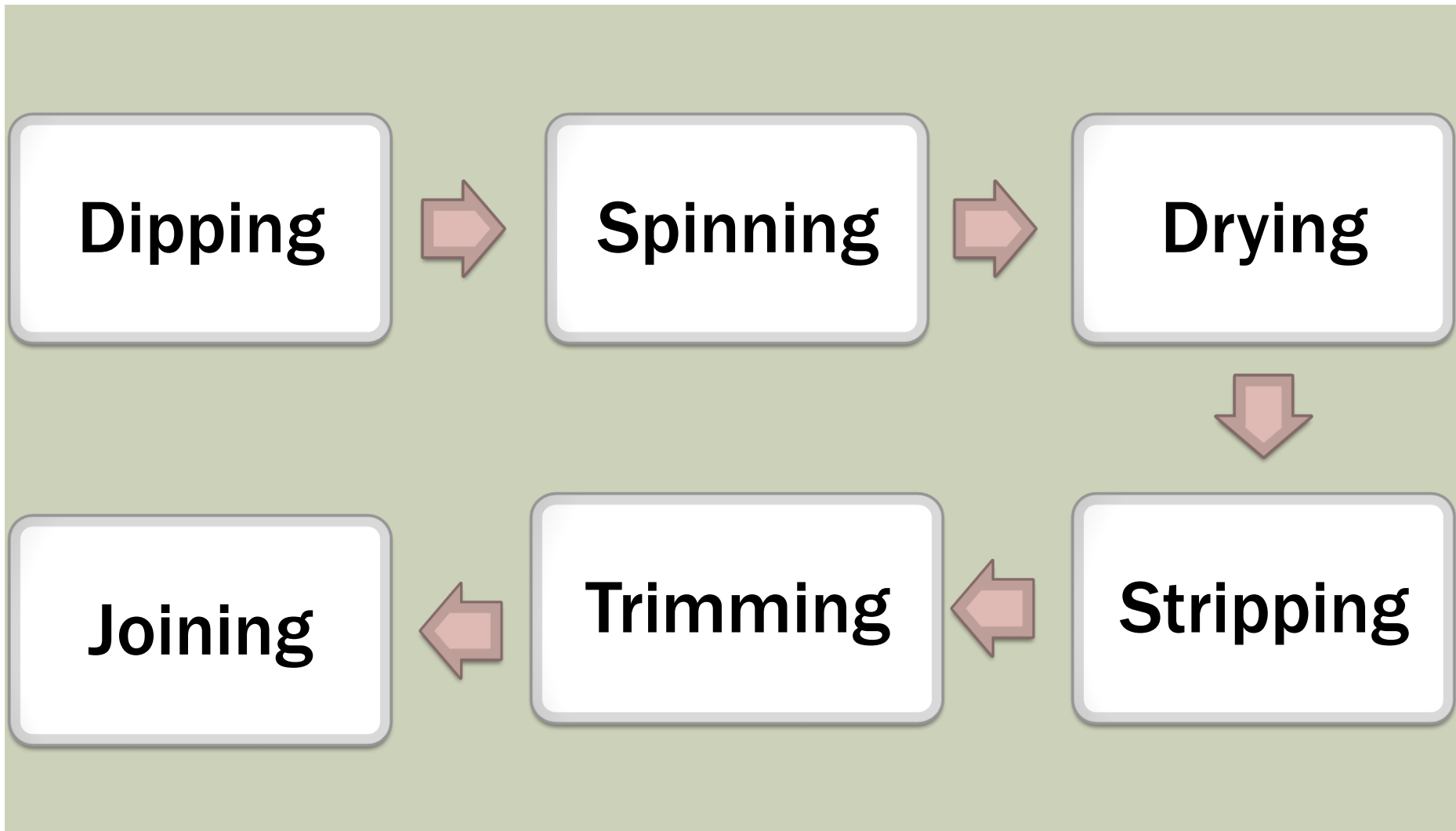
2- Manual filling machine which is used for small scale the produce 20-36 capsules.

3- Hand filling by the dipping technique.

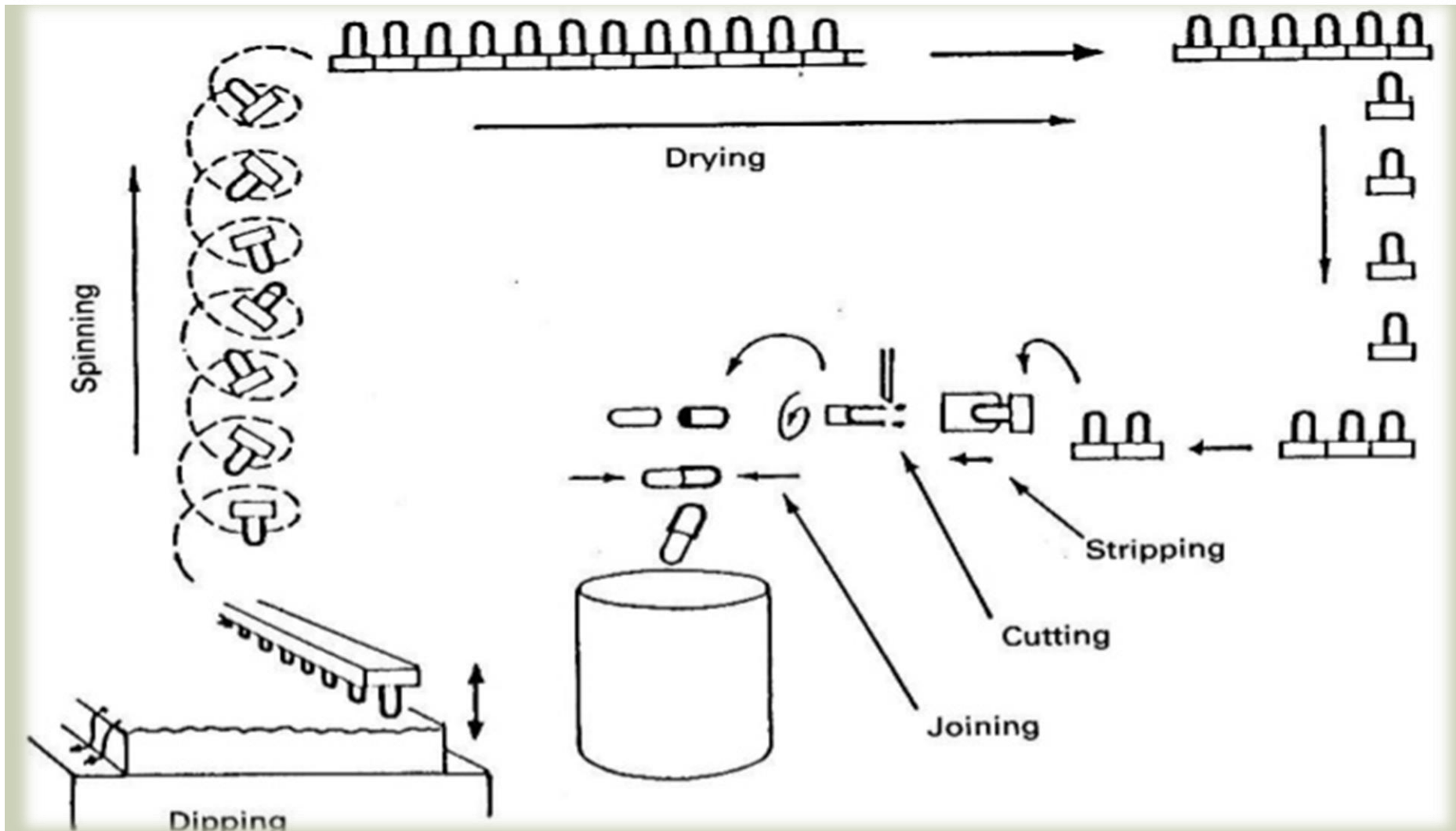


NOTE

THE PRODUCTION OF THE HARD GELATIN CAPSULE SHELL INVOLVE THE FOLLOWING STEPS:



STEPS OF HARD GELATIN CAPSULE SHELL PRODUCTION



STEPS FOR PREPARATION

1- **Salt polishing** as NaCl granules in a pan, but this method has the disadvantage of causing salty taste and removing the imprinting from the capsule.

3- **Pan polishing** by using a piece of cloth that must contain oil to be placed in a pan (coating pan).

C- Polishing (finishing)

2- **Cloth polishing** by a piece of cloth which may or may not contain oil, the oil here is used to give the capsule an elegant and shiny shape.

4- **Brushing** the use of a rotating soft brush.

EVALUATION OF CAPSULES

1- Weight variation test:

It's done by taking **20 capsule** individually weighed and the **average weight** is determined. If **2 capsules** fall outside the range of **10% of the average** then should take another **40 capsules** then determine the average of **60 capsules**, the test requirement are met if **6 capsules** fall outside the **10% of the average** and **none** of the **6 capsules** outside **25% range**.

EVALUATION OF CAPSULES

2- Content uniformity test:

It's done by taking **10 capsules** and assay each individually by specified procedure, if **9 out of 10** within the requirement of **$\pm 15\%$ (85%-115%)** limits and the **tenth** tablet is not outside **$\pm 25\%$ (75%-125%)** so the batch should be accepted.

While if **2 capsules** out of **10** fall outside the range **$\pm 15\%$** so take **20 capsules** and assay them individually and take the **average of 30 capsules**, so the requirements are met if **27 capsules** in the **$\pm 15\%$** range and only **3 capsules** in the **$\pm 25\%$** range.

EVALUATION OF CAPSULES

3- Disintegration test:

The disintegration time is measured when the capsule shell ruptures and all the contents pass through the mesh, in order for the batch to be **accepted the time must be less than 30 minutes.**

THE FACTORS AFFECTING THE DISINTEGRATION TIME

1- The type of the gelatin shell.

2- The humidity of the capsule shell.

3- Dissolution media.

4- The type of the powder used.

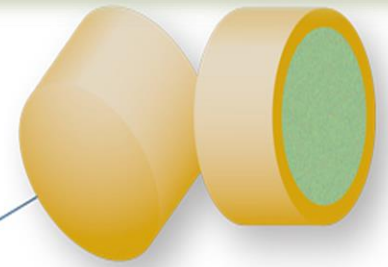
5- The type and the amount of the binder used.

SPECIAL TECHNIQUES USED IN THE CAPSULE MANUFACTURING

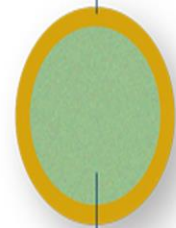
- **1- Imprinting:** which is done by imprinting the company name or symbol &/or the product identification code best to be applied on empty capsule.
- **2- Special purpose capsule:** which is used to produce capsules with special treatment to **retard the solubility** of the gelatin or to provide **enteric properties**, this is done by the **formalin** treatment of the gelatin that will cause the **cross linking** of the gelatin molecules.
- **3- Separation of the incompatible ingredients:** which consist of **2 phase capsule** the first phase is either **SGC or small coated tablet or pill or small HGC** that are filled in the capsule then the **second phase** which is **powder is added** into the capsule in the **usual manner**.



Capsule



Release-Control Polymer



Mini Tablet (Granulation or Hydrophilic Matrix)



THANK YOU

A watercolor illustration featuring the words "THANK YOU" in a black, serif, all-caps font. The text is arranged in two lines: "THANK" on the top line and "YOU" on the bottom line. The words are surrounded by a delicate arrangement of autumn-themed elements. Several leaves in shades of red, pink, and orange are scattered around the text, some with white vein patterns. Small clusters of green berries are also visible, particularly near the top right and bottom center. The overall style is soft and artistic, with a white background.